

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

<b>IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION</b>  <b>THIS DOCUMENT RELATES TO: All Direct Purchaser Actions</b>	<b>Case No. 1:15-cv-07488-CM-RWL</b>
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**PLAINTIFFS' OPPOSITION TO FOREST'S MOTION *IN LIMINE*  
NO. 13 TO PRECLUDE PREJUDICIAL AND IRRELEVANT EVIDENCE AND  
ARGUMENT REGARDING FOREST'S MEDICAID REBATE SAVINGS**

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**I. INTRODUCTION**

Plaintiffs respectfully submit this Opposition to Forest’s Motion *in Limine* No. 13 to Preclude Prejudicial and Irrelevant Evidence and Argument Regarding Forest’s Medicaid Rebate Savings (ECF No. 792).

Plaintiffs contend that Forest made a large and unexplained reverse payment to Mylan for the purpose of delaying generic Namenda IR entry. Forest conveyed its payment to Mylan via compensation terms in an amendment to a pre-existing agreement that allowed Mylan to sell an authorized generic version of Forest’s drug Lexapro (the “Lexapro Amendment”). Forest and Mylan executed the Lexapro Amendment on the same day as they executed the agreement to settle the Namenda patent litigation, and three years after the effective date of the Deficit Reduction Act of 2005 (the “DRA”).

Forest argues that the Lexapro Amendment did not convey a reverse payment but rather provided substantial value to Forest by reducing the Medicaid rebate liability that Forest would owe pursuant to the DRA. Forest moves to exclude Plaintiffs from introducing evidence or argument: (1) related to Congress’s intent in passing the DRA, (2) that suggests that the Lexapro Amendment enabled Forest to exploit a loophole in the law or otherwise underpay Medicaid, and (3) that suggests that Forest took money from the government, taxpayers, and Medicaid-eligible individuals. Defs.’ Br. at 1 (ECF No. 793).

As an initial matter, there is a threshold question of whether the potential reduction of Forest’s Medicaid rebate liability is a cognizable justification for a reverse payment by a brand company to a generic challenger (here, Mylan) under *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013) (“*Actavis*”), which specifically distinguishes payments by the brand to the generic challenger that seek to induce the generic challenger to abandon its claim (unlawful and anticompetitive) versus

potentially justifiable payments to the generic challenger that reflect the fair value of compensation for services the generic has promised to perform in exchange for payment.

The importance of the payment's effect as an inducement to the generic challenger was heavily contested on summary judgment in this case. In its ruling on those motions, this Court recognized that the focus must be on whether the generic challenger was induced to delay. *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 197 (S.D.N.Y. 2018) (“*Namenda V*”) (*quoting Actavis*, 570 U.S. at 155) (“Reverse payments are of particular concern when they demonstrate ‘that the patentee [sought] to induce the . . . [infringer] to abandon its claim with a share of its monopoly profits that would otherwise be lost in a competitive market.’”). Other courts also have reached this conclusion. *See In re Loestrin 24 Fe Antitrust Litig.*, MDL No. 13-2472-S-PAS, 261 F. Supp. 3d 307, 332 (D.R.I. Aug. 8, 2017) (“The [Supreme] Court’s use of the word ‘induce’ suggests that the value to the alleged infringer is paramount, whereas the emphasis on the ‘share of its monopoly profits’ supports the notion that the brand must be alleged to have sacrificed some amount of its anticipated profits in order to maintain its monopoly.”); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015) (“As *Actavis* explains, the relevant inquiry is what would induce *the generic* to stay off of the market. A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim.”) (internal citations omitted) (emphasis in original).

Consistent with this Court’s summary judgment ruling and the established jurisprudence, Plaintiffs’ Motion *in Limine* No. 7 seeks to exclude all evidence regarding Forest’s Medicaid rebate liability because it is unrelated to the value of services that Mylan promised to perform

pursuant to the Lexapro Amendment. *Actavis*, 570 U.S. at 156 (a payment may be explained if it “reflect[s] compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item.”). Whether the Lexapro Amendment provided an ancillary financial benefit to Forest from the government has no bearing on whether Forest’s payment induced Mylan to abandon its challenge to Forest’s patent.

Assuming *arguendo*, however, that the jury is allowed to consider evidence and argument from Forest about its anticipated Medicaid rebate liability savings as a result of the Lexapro Amendment, then Plaintiffs should not be precluded from providing the jury with appropriate background information about Medicaid, Medicaid rebate liability, and the DRA so that the jury can make a fully informed determination about Forest’s \$32.5 million payment to Mylan under the Lexapro Amendment. Specifically, the jury should be given the evidence it needs to understand how the Medicaid rebate program works with respect to authorized generics to determine whether Forest’s purported rebate savings represented “fair value” for Mylan’s services or whether Forest merely used its purported savings (which Forest forecast as roughly equivalent to the reverse payment amount) as a funding source to pay Mylan. *See Namenda V*, 331 F. Supp. 3d at 199.

## **II. FACTS**

The Lexapro Amendment altered the Distribution and Supply Agreement (Generic Lexapro) (the “Original Lexapro Agreement”) between Forest and Alphapharm Pty, Ltd. (“Alphapharm”), which Mylan later acquired. The Original Lexapro Agreement was executed on October 3, 2005 in connection with settlement of Hatch-Waxman litigation concerning that drug. *See* Revised Pls.’ Contentions (“DPP Cont.”), ECF No. 699-1 at ¶ 128.

The compensation terms of the Original Lexapro Agreement provided for Alphapharm and Forest to share the profits associated with Alphapharm's sales of Authorized Generic Lexapro, with Alphapharm entitled to 60% and Forest entitled to 40%. *Id.*

The Lexapro Amendment, which the parties executed on June 21, 2010 (the same day that the Namenda litigation settlement agreements were executed), provided that Mylan rather than Forest would manufacture the authorized generic Lexapro product that Mylan would sell, altered the compensation terms of the Original Lexapro Agreement such that Mylan's share of the profits on the first \$150M in Authorized Generic Lexapro sales would be increased by \$12.5 million, and provided for a \$20 million cash payment from Forest to Mylan within ten days of execution of the agreement. *See* DPP Cont. at ¶¶ 129, 141.

Forest claims that the payment it made to Mylan in connection with the Lexapro Amendment can be explained, in part, by the Medicaid rebate savings that Forest projected it would achieve when Mylan took over the manufacturing of Authorized Generic Lexapro. Defs.' Br. at 2. (In Plaintiffs' Motions *in Limine* Nos. 6 and 7, Plaintiffs explained that Medicaid rebate savings are not a cognizable explanation under *Actavis* or the rule of reason in general.) (ECF Nos. 744 and 745).

Medicaid is a joint federal and state program created in 1965 and managed by Centers for Medicare and Medicaid Services ("CMS") "that provides health coverage to tens of millions of lower-income Americans, including children, pregnant women, parents, seniors and individuals with disabilities." Toto Decl. Ex 2, ECF No. 794-2, Excerpts of Expert Report of Forest's Expert Alexandra Mooney Bonelli ("Bonelli Rpt.") at ¶ 7.

In 1990, Congress established the Medicaid Drug Rebate Program ("MDRP") in an effort to reduce the federal and state cost of providing prescription drug coverage to Medicaid

beneficiaries. The MDRP is structured to achieve such cost reduction through the use of a rebate system (known as the “Medicaid rebate”), whereby a participating manufacturer must pay a rebate to the state Medicaid agency after the state Medicaid agency has paid for the drug – in essence offsetting or reducing the amount the state Medicaid agency has paid for the drug. *Id.* at ¶ 8.

Every manufacturer participating in the MDRP must pay a rebate for each unit of the manufacturer’s covered outpatient drug paid for by a state Medicaid agency. Rebates are paid by participating drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to help “offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients.” *Id.* at ¶ 9, quoting the CMS website (<https://medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>).

The per-unit rebate amount, which is calculated by CMS, is tied to the product’s commercial price in the market; therefore, manufacturers must report to CMS certain pricing data based upon their commercial sales and discounts in order for CMS to be able to calculate the rebate amounts. Under applicable rules and regulations, a manufacturer of brand drugs must report its “Best Price” and other pricing data within 30 days after the end of each calendar quarter. *Id.* at ¶ 15. In general, “Best Price” reflects the lowest price available from a manufacturer to a commercial customer in the United States. *Id.* at ¶ 17.

Prior to the DRA, there were no statutory requirements specifically addressing authorized generics under the MDRP. As such, an authorized generic drug was commonly treated as a separate drug from its related brand counterpart for price reporting purposes, and specifically for the Best Price calculation. *Id.* at ¶ 21. The DRA, which largely became effective on January 1,

2007, amended the statutory definition of Best Price by specifying that Best Price must include the lowest price of an authorized generic drug. *Id.* at ¶ 22.

### III. ARGUMENT

Evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence and the fact is of consequence in determining the action. Fed. R. Evid. 401. Relevant evidence is generally admissible. Fed. R. Evid. 402. “Evidence need not be conclusive in order to be relevant.” *United States v. Schultz*, 333 F.3d 393, 416 (2d Cir. 2003) (quoting *Contemporary Mission v. Famous Music Corp.*, 557 F.2d 918, 927 (2d Cir. 1977)). As the Second Circuit explained, “[A] district court ‘may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.’ Fed. R. Evid. 403. But in reviewing a district court’s Rule 403 ruling, we ‘generally maximiz[e] [the evidence’s] probative value and minimiz[e] its prejudicial value.’” *United States v. Monsalvatge*, 850 F.3d 483, 494 (2d Cir. 2017) (citations omitted) (alterations in original).

As noted above, this Court specifically recognized in its recent summary judgment ruling that the focus of an *Actavis* claim is whether the generic was induced by the payment. *See supra* at 2; Pls.’ Mot. *in Limine* No. 7 (ECF No. 745). Whether it was a good deal for the brand is irrelevant. *See* Pls.’ Mot. *in Limine* No. 6 (ECF No. 744) at 4-7. Here, Forest claims that it anticipated a \$25+ million reduction in its Medicaid rebate liability associated with its future Lexapro brand sales as a result of transferring the manufacturing of the authorized generic to Mylan, and that this reduction allegedly justifies in part its payment of \$32.5 million to Mylan upon the execution of the Lexapro Amendment. Because of this asserted justification, whether the Lexapro Amendment was merely a means to disguise a payment to induce Mylan to quit its

patent challenge or whether the Lexapro Amendment payments to Mylan represented fair value for services that Mylan rendered are key issues in the *Actavis* reverse payment analysis. *See Namenda V*, 331 F. Supp. 3d at 199 (“Plaintiffs argue that [Forest’s Medicaid rebate liability] reduction was both inflated and pretextual . . . Plaintiffs have presented enough evidence that rebuts Defendants’ procompetitive justifications to get to trial.”).

In order to make these determinations regarding Forest’s claimed justification involving the amount of its anticipated Medicaid rebate liability, the jury will need to understand what Medicaid is, what rebate liability is, how rebate liability worked prior to the DRA (when the Original Lexapro Agreement was executed), how the DRA changed the treatment of authorized generics for the purpose of rebate liability calculations, why the Lexapro Amendment would potentially reduce Forest’s liability, and whether the reduction in Forest’s rebate liability corresponded with any increase in liability or burden for Mylan (*i.e.*, whether the value of services that Mylan provided was related to the expected reduction in Medicaid liability) or was instead merely an ancillary benefit to Forest.

Additionally, what Forest knew about rebate liability laws/regulations and when it knew it goes to the credibility of Forest’s argument that the Lexapro Amendment was independent of the Namenda patent settlement. Specifically, Forest could have, but did not, seek to achieve the same purported savings through an amendment to the Original Lexapro Agreement until it was *also* negotiating with Mylan over the Namenda patent settlement. Relevant evidence would therefore include Forest’s monitoring of the 2005 DRA legislation before the Original Lexapro Agreement in 2005, Forest’s failure to approach Mylan to amend the Lexapro deal from 2005 to 2009, and Forest’s waiting to raise the Lexapro Amendment with Mylan until the Namenda settlement despite having ongoing business relations with Mylan with regard to another drug,

Nebivolol, in 2008 (*see, e.g., Mylan Inc. v. Commissioner*, Nos. 16145-14, 27086-14, 2016 Tax Ct. Memo LEXIS 45, at \*8-11 (T.C. Mar. 10, 2016)).

Plaintiffs do not intend to mischaracterize the Lexapro Amendment as illegally, fraudulently or illicitly depriving Medicaid or its recipients of funds, but the fact that the DRA amended the statutory definition of “Best Price” by specifying that it must include the lowest price of an authorized generic drug is essential to understanding the nature of the value of the Lexapro Amendment and evaluating whether the timing of the DRA in relation to the Lexapro Amendment and the Namenda settlement suggests that the Lexapro Amendment is merely a cover for a payment to Mylan.

In general, evidence regarding the Medicaid rebate liability and the DRA is not prejudicial and clearly probative (assuming Forest’s rebate liability reduction defense is cognizable at all under *Actavis*). Evidence and argument related to public statements by members of Congress or in congressional hearings concerning the purpose of the DRA (*e.g.*, to close a loophole under which brand companies were not paying rebates on sales of their authorized generics) are relevant to show that Forest knew or should have known of the potential change in the law long before it approached Mylan in early 2010 about amending the Original Lexapro Agreement, or even before it signed the Original Lexapro Agreement. *See, e.g., The President’s Budget Proposals for Fiscal Year 2006, Hearing Before the Committee on Finance United States Senate*, 109th Cong. 38-39 (2005), available at <https://www.finance.senate.gov/imo/media/doc/25948.pdf>; 151 Cong. Rec. S12122, (Nov. 1, 2005), available at <https://www.govinfo.gov/content/pkg/CREC-2005-11-01/pdf/CREC-2005-11-01.pdf>. And while Plaintiffs do not intend to present evidence or argument that *Forest* exploited a loophole in the DRA, evidence that members of Congress were publicly discussing

the need to close what they described as a loophole in the MDRP by passing the changes contemplated in the DRA is relevant to show Forest's failure to act on the issue (by approaching Mylan or a third party about a manufacturing site transfer for an authorized generic version of Lexapro) until it needed a cover to pay Mylan. *See, e.g., The President's Budget Proposals for Fiscal Year 2006, Hearing Before the Committee on Finance United States Senate, 109th Cong. 38-39 (2005), available at <https://www.finance.senate.gov/imo/media/doc/25948.pdf>; 151 Cong. Rec. S12122, (Nov. 1, 2005), available at <https://www.govinfo.gov/content/pkg/CREC-2005-11-01/pdf/CREC-2005-11-01.pdf>; Declaration of Joseph Oppen ("Oppen Decl.") Ex. 42, PX-1411 (article regarding best price reporting for authorized generics); Oppen Decl. Ex. 43, PX-1410 (notice that authorized generics likely to be considered in best price calculations). Forest's own expert admitted that Forest's "legal department was probably following Congress." Oppen Decl. Ex. 44, Bonelli Tr. at 102:2-103:5.*

Finally, with respect to evidence or argument suggesting that Forest's Medicaid rebate savings would otherwise have been conferred to the government, taxpayers, and Medicaid-eligible individuals, Plaintiffs reiterate that they do not intend to present argument or evidence that the Lexapro Amendment illegally, fraudulently or illicitly deprived Medicaid or its beneficiaries of money. However, the essence of Forest's purported justification for the payment to Mylan is that Forest thought the Lexapro Amendment would reduce its payments under the Medicaid Drug Rebate Program. Forest claims that *Plaintiffs* intend to "focus on irrelevant and prejudicial characterizations" that Medicaid "provides health coverage to tens of millions of lower-income Americans, including children, pregnant women, parents, seniors and individuals with disabilities," and that Forest's Medicaid rebate savings would have otherwise gone to reimburse that program. Defs.' Br. at 1, 6. ***But those characterizations are verbatim from***

**Forest's expert.** See Toto Decl. Ex 2, ECF No. 794-2, Excerpts of Bonelli Rpt. ¶¶ 6, 7, 29. If Forest believes that those facts are too prejudicial, then it should not open the door by offering its expected Medicaid rebate liability savings as a purported justification for the payment. If Forest believes that its own expert's opinions are prejudicial to it, it should withdraw them.

The cases Forest cites, in which courts precluded potentially inflammatory and misleading evidence, therefore are not relevant here. In *U.S. Bank Nat'l Assn. v. PHL Variable Life Ins. Co.*, 112 F. Supp. 3d 122, 138-40 (S.D.N.Y. 2015), U.S. Bank filed a motion *in limine* to preclude defendant Phoenix from disparaging U.S. Bank for investing in life insurance policies and in distressed assets. *Id.* at 138-39. At issue there was the admissibility of evidence regarding STOLI policies (life insurance policies procured and sold to investors with no insurable interest in the life of the insured) and life settlement investments. *Id.* at 139. This Court found that evidence regarding STOLI policies was entirely irrelevant to the case and would be inflammatory because “the idea that there is an entire industry built on profiting from death is highly prejudicial—so prejudicial that the very idea of it has been declared void for public policy in many states.” *Id.* While STOLI transactions are legal in New York, this Court found that evidence thereof in that case would result in prejudice “that does not derive from proof relevant to the issues in the case.” *Id.* While barring inflammatory rhetoric, such as references to “death profiteering” or “inequitable conduct,” this Court did, however, allow for evidence regarding life settlement investments to be introduced, noting that “[t]o understand that claim, the jury will, of course, need background about life settlement practices—i.e., purchasing and bundling life insurance policies as an investment vehicle.” *Id.* at 139-40.

In the instant case, Plaintiffs will introduce no such inflammatory language. Further, the subject matter—the history of and intent behind the passage of the DRA—is not at all

comparable to evidence about an insurance practice found so repugnant that many states have deemed it void as against public policy, and Forest has not explained how the introduction of such would prejudice it in any way. Moreover, as in the instant matter, this Court in *U.S. Bank* recognized the need for and importance of introducing background information to help a jury fully understand an issue with which they may not normally be familiar, such as the DRA. Plaintiffs will appropriately focus on the background of the DRA, Forest's expert's own characterizations and the necessary impact of Forest's conduct in light of those characterizations, all of which fall within the scope of Ms. Bonelli's expert report.

Forest's reference to *Hart v. RCI Hospitality Holdings, Inc.*, 90 F. Supp. 3d 250 (S.D.N.Y. 2015), is similarly unavailing. There, the Court did not allow quantification of performance fees earned by exotic dancers, in addition to their court-awarded minimum wage payments, for fear it would result in an emotional reaction or policy judgment by jury members. *Id.* at 260. Again, there is no similar risk of prejudice here, where the evidence at issue simply involves the history of and intent behind passage of a piece of legislation that Plaintiffs do not claim Forest violated, but that gave rise to Forest's own purported justification for the Lexapro Amendment, a justification which Plaintiffs are allowed to test if Forest is allowed to offer it.

Forest should not be allowed to present evidence and argument to the jury showing that it believed the Lexapro Amendment would save it millions of dollars on Medicaid rebate liability, but at the same time preclude Plaintiffs from explaining the facts and circumstances surrounding that belief. If Forest does not want the jury to hear that the Lexapro Amendment enabled it to pay millions less to government Medicaid programs (despite that being the very essence of Ms. Bonelli's opinion), it can choose not to argue that those savings justify its payment to Mylan.

#### IV. CONCLUSION

Forest's Motion *in Limine* No. 13 should be denied.

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 14, 2019, I electronically filed the above by the CM/ECF system.

Respectfully submitted,

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